



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MS

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

October 25, 2002

RE: Inspection ID - 1236950009

Mr. Gary D. Hallman
President and Chief Executive Officer
Medina General Hospital
1000 East Washington St.
Medina, OH 44256-2170

Dear Mr. Hallman:

Your mammography operation was inspected on August 15, 2002 by a representative from the Ohio Department of Health radiation control program under contract to the Food and Drug Administration or (of the Food and Drug Administration). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Section 900.12.

On October 8, 2002, you responded to the Warning Letter, dated September 17, 2002. Based on your response, your facility has now met the annual MQSA inspection requirement. The corrective action you have implemented will be evaluated during your next inspection.

Your response documents will be made a permanent part of our inspection file.

Sincerely yours,

R. Terry Bolen
MQSA Compliance Officer
Cincinnati District Office

c. OH/DWLeeseberg